USDA Foreign Agricultural Service
GAIN Report
Global Agriculture Information Network
Template Version 2.09

Voluntary Report - public distribution

Date: 8/7/2006

GAIN Report Number: E36113

EU-25

Food and Agricultural Import Regulations and Standards

Package of proposals for new legislation on food additives, flavorings and enzymes

2006

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Report Highlights:
A four-part package of legislative proposals concerning new legislation on food additives, flavorings and enzymes has been published. Three of the proposals are created in order to update the regulation on additives, food enzymes and flavorings and the fourth one to lay down a common approval procedure for these substances. It will take at least another 18 months before these proposals will become EU law.

Includes PSD Changes: No
Includes Trade Matrix: No
Unscheduled Report
Brussels USEU [BE2]
[E3]

Introduction
The European Commission has adopted a package of four legislative proposals updating existing regulations on food additives, food enzymes and flavorings and an introduction of a simplified common approval procedure for these substances. At the end of this report, details on the scope of each individual legislation are given in the annex containing the definitions of these substances.

Additives
The proposal on food additives would bring several current Directives together into one single regulation. If adopted, it would replace the framework additives Directive 89/107/EEC as well as the existing Directives on colors (Directive 94/36/EC), sweeteners (Directive 94/35/EC) and additives other than colors and sweeteners (Directive 95/2/EC).

The new legislation replacing Directive 89/107/EEC would introduce a simpler and faster food additive approval system. Under the current system provided by Directive 89/107/EEC, the Commission must obtain the consent of both the Council and the Parliament for the implementing proposal recommending approval of an additive. (This procedure is known as co-decision.)
Under the new legislation, the Commission would draft an implementing proposal for the approval of an additive and submit it to the Standing Committee on the Food Chain and Animal Health (SCFCAH). The SCFCAH is made up of officials from Member State ministries. (This procedure is known as comitology.)

Member State approval in the SCFCAH will be based on a safety evaluation conducted by the European Food Safety Authority (EFSA). Thus all applications for the approval of new food additives will be directed to EFSA to carry out the safety evaluations. At the same time a re-evaluation program will be introduced for food additives that are currently on the EU market, also based on risk assessments by EFSA.

Another objective of the proposal is to require authorization of additives that consist of, contain or are produced from genetically modified organisms (GMO). These additives should be authorized under Regulation (EC) No 1829/2003 on genetically modified food and feed prior to their inclusion in the positive list under this Regulation. This rule also applies to food enzymes and flavorings.

Enzymes
This proposal would introduce the regulation of food enzymes for the first time at EU level. Currently, only two food enzymes used as food additives are authorized under the food additive legislation, while the remaining enzymes are not regulated at all or are regulated as processing aids under Member States' legislation (note: Processing aids fall outside the scope of the EU food additives regulation and therefore did not require EU approval until now). However, some Member States have specific regulations on these products which will require harmonization across the EU-25.

Since a considerable number of food enzymes are already on the market, a period of 24 months is provided for the submission of applications of existing enzymes. An initial community list will be established after evaluation by EFSA. The approval system and positive list will be similar to those for additives. Requirements for the labeling of food enzymes other than those used as processing aids are included in the proposal as well.

Flavorings
The new proposal would update the current Directive 88/388/EEC on flavorings to cope with technological and scientific developments. The rules on maximum levels are clarified, as

well as definitions of flavorings. Stricter conditions are introduced for the use of the term "natural" when describing flavorings.

Common Authorization Procedure
The key issue of these proposals is the introduction of a single common procedure for the approval of food additives, flavorings and enzymes. This last proposal backs up the first three proposed regulations since it contains procedural rules, such as time limits for handling applications and the format to be used for submission of the applications.

The benefits of this common approach include simplified legislation and more consistency in the procedures used to approve additives, flavorings and enzymes. A great deal of importance will also be attached to the safety evaluations that will be conducted by EFSA.
See also: http://ec.europa.eu/food/food/chemicalsafety/additives/prop_leg_en.htm

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ANNEX

The following definitions on **food additives** shall apply:

(a) 'food additive' shall mean any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food, whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods; however, the following are **not** considered to be food additives:

(i) foods containing monosaccharides, disaccharides or oligosaccharides used for their sweetening properties;
(ii) foods, whether dried or in concentrated form, including flavourings incorporated during the manufacturing of compound foods, because of their aromatic, sapid or nutritive properties together with a secondary colouring effect;
(iii) substances used in covering or coating materials, which do not form part of foods and are not intended to be consumed together with those foods;
(iv) products containing pectin and derived from dried apple pomace or peel of citrus fruits, or from a mixture of both, by the action of dilute acid followed by partial neutralisation with sodium or potassium salts ('liquid pectin');
(v) chewing gum bases;
(vi) white or yellow dextrin, roasted or dextrinated starch, starch modified by acid or alkali treatment, bleached starch, physically modified starch and starch treated by amylolitic enzymes;
(vii) ammonium chloride;
(viii) blood plasma, edible gelatin, protein hydrolysates and their salts, milk protein and gluten;
(ix) amino acids and their salts other than glutamic acid, glycine, cysteine and cystine and their salts having no technological function;
(x) caseinates and casein;
(xi) inulin;

(b) 'processing aid' shall mean any substance which:
(i) is not consumed as a food by itself;
(ii) is intentionally used in the processing of raw materials, foods or their ingredients, to fulfil a certain technological purpose during treatment or processing; and
(iii) may result in the unintentional but technically unavoidable presence in the final product of residues of the substance or its derivatives provided they do not present any health risk and do not have any technological effect on the final product;

(c) 'functional class' shall mean one of the categories set out in Annex I based on the technological function a food additive exerts in the foodstuff;

(d) 'unprocessed food' shall mean a food which has not undergone any treatment resulting in a substantial change in the original state of the food, for which purpose the following in particular are not regarded as resulting in substantial change: dividing, parting, severing, boning, mincing, skinning, paring, peeling, grinding, cutting, cleaning, trimming, deep-freezing, freezing, chilling, milling, husking, packing or unpacking;

(e) 'food with no added sugars' shall mean a food without the following:
(i) any added monosaccharides, disaccharides or oligosaccharides; or
(ii) food containing monosaccharides, disaccharides or oligosaccharides which is used for its sweetening properties;

(f) 'energy-reduced food' shall mean a food with an energy value reduced by at least 30% compared with the original food or a similar product;

(g) 'table-top sweeteners' shall mean preparations of permitted sweeteners, which may contain other food additives and/or food ingredients and which are intended for sale to the final consumer as a substitute for sugar.

The following definition on **food enzymes** shall apply:

'food enzyme' means a product obtained by extraction from plants or animals or by a fermentation process using micro-organisms:

(a) containing one or more enzymes capable of catalyzing a specific biochemical reaction; and

(b) added to food to perform a technological function in the manufacture, processing, preparation, treatment, packaging, transport or storage of foods.

The following definitions on **flavorings** shall apply:

(a) 'flavorings' shall mean products:
(i) not intended to be consumed as such, which are added to food in order to impart odour and/or taste;
(ii) made or consisting of the following categories: flavoring substances, flavoring preparations, thermal process flavorings, smoke flavorings, flavor precursors or other flavorings or mixtures thereof;

(b) 'flavoring substance' shall mean a chemically defined substance with flavoring properties;

(c) 'natural flavoring substance' shall mean a flavoring substance obtained by appropriate physical, enzymatic or microbiological processes from material of vegetable, animal or microbiological origin either in the raw state or after processing for human consumption by one or more of the traditional food preparation processes listed in Annex II;

(d) 'flavoring preparation' shall mean a product, other than a flavoring substance, obtained from:
(i) food by appropriate physical, enzymatic or microbiological processes either in the raw state of the material or after processing for human consumption by one or more of the traditional food preparation processes listed in Annex II and/or appropriate physical processes;
and/or
(ii) material of vegetable, animal or microbiological origin, other than food, obtained by one or more of the traditional food preparation processes listed in Annex II and/or appropriate physical, enzymatic or microbiological processes;

(e) 'thermal process flavoring' shall mean a product obtained after heat treatment from a mixture of ingredients not necessarily having flavoring properties themselves, of which at least one contains nitrogen (amino) and another is a reducing sugar; the ingredients for the production of thermal process flavorings may be:
(i) food; and/or (ii) source material other than food;

(f) 'smoke flavoring' shall mean a product obtained by fractionation and purification of a condensed smoke yielding primary smoke condensates, primary tar fractions and/or derived smoke flavorings as defined in points (1), (2) and (4) of Article 3 of Regulation (EC) No 2065/2003;

(g) 'flavor precursor' shall mean a product, not necessarily having flavoring properties itself, intentionally added to food for the sole purpose of producing flavor by breaking down or reacting with other components during food processing; it may be obtained from:
(i) food; and/or (ii) source material other than food;

(h) 'other flavoring' shall mean a flavoring added or intended to be added to food in order to impart odour and/or taste and which does not fall under the definitions (b) to (g);

(i) ‘food ingredient with flavoring properties’ shall mean a food ingredient other than flavorings which may be added to food for the main purpose of adding flavor to it or modifying its flavor;

(j) ‘source material’ shall mean material of vegetable, animal, microbiological or mineral origin from which flavorings or food ingredients with flavoring properties are produced; it may be: (i) food; or (ii) source material other than food;
(k) ‘appropriate physical process’ shall mean a physical process which does not intentionally modify the chemical nature of the components of the flavoring and does not involve the use of singlet oxygen, ozone, inorganic catalysts, metal catalysts, organometallic reagents and/or UV radiation.